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Hologic, Inc.

6100 Technology Center Drive, Indianapolis, IN 46278 USA Main: +1.800.650.2169 Fax: +1.317.344.7600

## 510(k) Summary

**OWNER/OPERATOR:** 

Firm:

Hologic, Inc. – Suros Division

Address:

6100 Technology Center Drive

Indianapolis, IN 46278

Phone #: Fax #:

317-344-7500

Registration #: 3003862400

317-344-7697

**CONTACT:** 

Paula A. Gray

Senior Quality & Regulatory Consultant

Hologic, Inc. – Suros Division 6100 Technology Center Drive

Indianapolis, IN 46278 Phone: 317-344-7687

DATE:

12/06/2007

**DEVICE NAME:** 

Classification Name:

Marker, Implantable Radiographic

Common/Usual Name:

Tissue Site Marking System

Proprietary Name:

SeCurMark Biopsy Site Identification System

Device Class:

Class II

Description

Implantable Clip

Number

**NEU** 

21 CFR Ref.

878.4300

Performance Standards

No applicable performance standards established

PREDICATE DEVICES:

510(k)-Number

**Device Name** 

Device Manufacturer

Location

JAN - 4 2008

K062528

K042296

Tissue Site Marking

Hologic, Inc. – Suros Division

Indianapolis,

IN

System

**BiomarC** 

Carbon Medical

St. Paul, MN

Technologies, Inc.

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#### **DEVICE DESCRIPTION AND CHARACTERISTICS:**

The SeCurMark family of Tissue Site Marking Systems is composed of two components:

- an implantable component, composed of a bioabsorbable and permanent component, and
- a deployment device utilized for placement of the implantable component at the site of

This family of devices is intended for use with the manual method of deployment under the following imaging modalities: ultrasound, x-ray, magnetic resonance, and direct visualization. The device is intended for single patient use only.

#### **INTENDED USE:**

The Tissue Site Marking System is indicated for the permanent radiographic marking of sites in soft tissue.

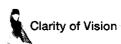
#### SUBSTANTIAL EQUIVALENCE:

Verification and validation testing has been conducted as part of the Suros divisions design control process and has proven that the SeCurMark family of devices is substantially equivalent to the predicates devices and is safe and effective for use.

### **CONCLUSION:**

Based on the information presented in this 510(k) submission, the SeCurMark Biopsy Site Identification System is substantially equivalent to the presently marketed predicate devices. No new safety or efficacy questions or risks are raised with the SeCurMark Biopsy System.







JAN - 4 2008

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Suros Surgical Systems, Inc. % Ms. Paula A. Gray Senior Quality & Regulatory Consultant 6100 Technology Center Drive Indianapolis, Indiana 46278

Re: K072913

Trade/Device Name: SeCurMark Biopsy Site Identification System

Regulation Number: 21 CFR 878.4300 Regulation Name: Implantable clip

Regulatory Class: II Product Code: NEU Dated: December 6, 2007 Received: December 7, 2007

Dear Ms. Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <a href="http://www.fda.gov/cdrh/industry/support/index.html">http://www.fda.gov/cdrh/industry/support/index.html</a>.

Sincerely yours,

Mark N. Melkerson

Mark I Milker

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): <u>K072913</u>
Device Name: <u>SeCurMark Biopsy Site Identification System</u>
Indications for Use:
The SeCurMark Tissue Site Marking System is indicated for the permanent radiographic marking of sites in soft tissue.
Prescription Use X Over-The-Counter Use (21 CFR 801 Subpart D)  AND/OR (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)
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MINIMUNE FOR M. MELKERSON
(Posted November 13, 2003)  (Division Sign-Off)  Division of General, Restorative,  and Neurological Devices
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